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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,764	09/18/2001	Mark de Boer	0925.009/11862US09	8879

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,764	BOER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8-11,29 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8-11,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant is reminded that this application is USSN 09/388,079 and not USSN 09/338,079, as indicated on the heading of applicant's communication, filed 1/18/01.

2. Applicant's communication, filed 9/18/01, has placed this application in compliance with the Sequence Rules.

3. Applicant's amendment, filed 9/18/02, has been entered.
Claims 1-5, 7 and 12-28 have been canceled.
Claims 29-30 hav been added.

Claims 6, 8-11 and 29-30 are pending.

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Also see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

5. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected

For the word "diease" should be "disease" on the first line of the Abstract.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6, 8-11 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating allergies as the IgE-mediated diseases, does not reasonably provide enablement for any treating any "IgE-mediated disease" with CD40-specific antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

The only IgE mediated disease disclosed by the instant specification is allergy. There is insufficient guidance and direction for the skilled artisan in determining the scope or patient populations that are targeted by the claimed methods, other than allergic patients.

As indicated below, the metes and bounds of IgE-mediated diseaes is indefinite.

For example, hyper-IgE syndrome is characterized by recurrent staphyloccocal infections, particulalry of the skin and markedly elevated levels of IgE (see Merck Manual of Diagnosis and Therapy, edited by Berkow et al., Merck Research Laboratories, Rathway, NJ, 1992, see page 316). Treatment consists of antibiotics. The skilled artisan would not predict that the adminsitnarion of anti-CD40 antibodies would result in treatment of hyper-IgE syndrome, wherein the target of therapy is the recurrent staphylococcal infection.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970).

Without sufficient guidance, using antio-CD40 antibodies to inhibit any "IgE-mediated disease" would have been unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

9. Claims 6, 8-11 and 29-30: 5D12, 3A8 and 3C6 antibodies.

It is apparent that the 5D12, 3A8 and 3C6 antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

Given the patented claims set forth in U.S. Patent No., 6,004,552 the requirement for the deposit of the biological materials 5D12, 3A8 and 3C6 antibodies under 35 USC § 112, first paragraph, enablement, has been satisfied.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

10. Claims 6, 8-11 and 29-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 6, 8-11 and 29-30 are indefinite in the recitation of "5D12", "3A8" and "3C6" because their characteristics are not known. The use of "5D12", "3A8" and "3C6"" monoclonal antibodies as the sole means of identifying the claimed antibodies renders the claims indefinite because these are merely laboratory designations which do not clearly define the claimed products, since different laboratories may use the same laboratory designations to define completely distinct cell lines.

Amending the claims to recite the appropriate ATCC Accession Numbers would obviate this rejection.

B) Claims 6, 8-11 and 29-30 are indefinite in the recitation of "IgE-mediated diseases" because the metes and bounds of said diseases is unclear and ambiguous. It is unclear what is considered an IgE-mediated disease, other than allergies.

For example, it is unclear whether hyper-IgE syndrome is characterized by recurrent staphyloccocal infections, particulalry of the skin and markedly elevated levels of IgE (see Merck Manual of Diagnosis and Therapy, edited by Berkow et al., Merck Research Laboratories, Rathway, NJ, 1992, see page 316).

It is noted that the instant specification does not appear to disclose IgE-mediated diseases other than allergies (e.g. see .

C) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

10. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 6, 8-11 and 29-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,004,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant IgE mediated diseases or allergies are an obvious targeted therapeutic conditions associated with inhbiting the growth and differantion fo human B cells or antibody production with anti-CD40 antibodies of the patented claims. In addition, whent eh claims are read in light of the specification, treating IgE-mediated diseases or allergies is contemplated by methods of inhibiting antibody-mediated diseases (e.g. see Field of the Invention, Summary of the Invention or Formulations and Methods of Administration of the instant specification).

12. No claim allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9306.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
September 26, 2003